IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CELSIS IN VITRO, INC. a Maryland Corporation, *Plaintiff,* v. CELLZDIRECT, INC., a Delaware Corporation and wholly-owned subsidiary of INVITROGEN CORPORATION; and INVITROGEN CORPORATION, a Delaware Corporation. *Defendants.*	)	Case No. _____

DECLARATION OF DANIEL DRYDEN

I, Daniel Dryden, declare as follows.

1. I am the Director of Product Operations for Celsis In Vitro, Inc. ("Celsis IVT"), which was formerly known as In Vitro Technologies, Inc. ("IVT"). In this capacity, I supervise and direct Celsis IVT's product development by improving existing products and evaluating new ones, among other things. I have personal knowledge of the facts stated in this Declaration and am able to testify competently to those facts.

A. History of IVT

2. In 1990, Dr. Paul Silber founded IVT, the predecessor of Celsis IVT, to provide *in vitro* testing services for cosmetic companies seeking to reduce live animal testing.

3. In the mid-1990's, Dr. Silber and IVT identified a target market consisting of chemical and pharmaceutical companies who needed outside laboratories to provide *in vitro* testing services and products. IVT began servicing the needs of these companies by providing *in vitro* testing. Then, IVT began selling *in vitro* products to pharmaceutical companies who conducted their own in-house *in vitro* testing. IVT also aligned with an Organ Procurement Organization ("OPO") in order to provide much sought after human-based *in vitro* test systems and products.

4. Throughout the 1990's, IVT continued to grow and service more pharmaceutical customers. As contract work began to diminish as pharmaceutical companies began shifting to in-house *in vitro* testing, IVT began focusing on the sale of human-based *in vitro* testing products.

5. For example, IVT began selling human liver microsomes and animal liver microsomes to customers for use in *in vitro* testing. Microsomes, which are liver cell fraction *in vitro* models, are not live cells, and therefore, are not ideal models for all *in vitro* testing. In particular, of IVT's two main markets for the sale of liver-based *in vitro* products (*i.e.*, toxicology and drug metabolism), only the drug metabolism market could utilize non-living cell fractions. Recognizing this early problem, IVT endeavored to provide customers with live cell testing or the live cells themselves. But, IVT faced

several hurdles because hepatocytes were difficult to isolate and had to be utilized right after isolation. To overcome these problems, IVT worked diligently to optimize its hepatocyte preservation techniques.

6. By 1997 and 1998, IVT was one of the few companies in the United States to have optimized the cryopreservation of hepatocytes. After the optimization of cryopreservation of hepatocytes, the use of hepatocytes in *in vitro* models became more reliable, because cryopreservation enabled the preservation of live cells for later use. Then in 2006, the FDA issued a report indicating that hepatocytes were the preferred model for some pre-clinical *in vitro* testing (*e.g.*, induction studies) and that the FDA considered there to be no difference between fresh and cryopreserved hepatocytes. After this report, IVT's sales of cryopreserved hepatocyte products continued to increase.

B. The Identification and Resolution of Problems Relating to Cryopreserving Hepatocytes

7. Even though the use of cryopreserved hepatocytes in *in vitro* testing was expanding, IVT continued to identify problems associated with their preservation and use. Similar to how IVT sought to optimize the preservation of hepatocytes in the mid-1990's, IVT attempted to solve these then-current problems. For example, cryopreserved hepatocytes failed to attach to collagen-coated plates for long-term studies. IVT resolved this problem and began offering "plateable" cryopreserved hepatocytes, which were cryopreserved hepatocytes that attached to collagen-coated plates after they were thawed. Although IVT experienced some initial skepticism among its customers, these customers eventually embraced the performance of these products (as well as the major advantage of not having to wait for fresh cells to become available).

8. As another example, the then-current cryopreservation methods did not allow for multi-donor hepatocyte pools. These pools were desired among researchers, because the variety of cells (*i.e.*, male, female, old, young, healthy, unhealthy) helped eliminate the effects of outlier data in research results. The only way for a researcher to work with multi-donor human hepatocyte preparations was to purchase cryopreserved hepatocyte samples from multiple donors and then mix them in their labs by thawing the vials and mixing together the thawed cells. Researchers widely believed that re-cryopreservation of hepatocytes would cause significant damage. Thus, each time a researcher would thaw multiple liver cell vials for mixing, she would discard the unmixed cells which were not utilized in experimentation. For example, if a researcher created a pool from five individuals using five vials of individual hepatocytes containing at least five million cells, yet only needed 10 million hepatocytes from the 25 million hepatocyte yield, she would effectively waste 60% of the mixture.

9. This lack of multi-donor pools was compounded when working with human liver cells, because unlike research animal liver cells—which are abundant and available at any time for use by a researcher—there were scarce opportunities to obtain multiple human liver cells simultaneously and then mix them together in a vial for at least two reasons. First, the supply of human liver cells was greatly diminished because of the rate-limiting factor of available human liver tissue. Second, human liver cells were very fragile and must be harvested within a very short time from leaving the body to maintain the viability of the cells. Thus, even if two human livers became available within a single day, there would not be enough time to create a multi-donor pool. And even if that

would work, a sample of only two different liver cells was not diverse enough to eliminate the effects of outlier data.

10. Beginning in April 2004, my then-colleague James Hardy and myself sought to resolve these problems and create multi-donor hepatocyte pools that were strong enough to survive the effects of multiple cryopreservation steps. We used our experience and developed a novel process for producing a multi-donor hepatocyte product using, in general, the steps of cryopreserving individual sources, thawing them, forming a pool, removing non-viable cells and debris, and then re-cryopreserving the hepatocytes for storage and then their later use. IVT named this process the LiverPool™ method, and the resulting multi-donor hepatocyte product the LiverPool™ product. Shortly thereafter, IVT filed patent applications on this new technology and the first application issued as U.S. Patent No. 7,604,929 ("the '929 patent") in October 2009.

11. The inventors of the '929 patent are James Hardy and myself. Mr. Hardy holds a bachelors degree in biology with a chemistry minor from Whittenberg University and possessed at least two years of experience with cryopreserved hepatocytes at the time of the first-filed patent application. I hold a bachelors degree in chemistry from the University of Maryland and possess over a decade of experience with cryopreserved hepatocytes.

C. The LiverPool™ Products

12. From the time Celsis IVT first began its efforts to develop the technology behind the LiverPool™ products until the present, Celsis IVT has invested tens of thousands of dollars in equipment, materials, and resources, devoted hundreds of man hours, expended thousands of dollars in legal costs, and employed numerous sales and

marketing personnel—all of which do or have supported the LiverPool™ products. Through these efforts the LiverPool™ products have become the flagship products of Celsis IVT.

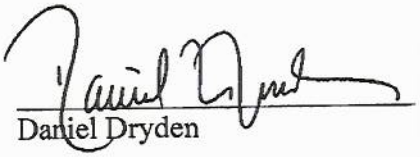
13. The LiverPool™ products provide researchers several advantages. One advantage is the reduced number of wasted cells for our customers. The LiverPool™ method allows for the production of vials containing only 5 million cells per vial from a mixture of individual donors. The LiverPool™ lots may be 5-, 10-, 20- and 50-donor pools, as well as single gender pools. These configurations allow the researcher to thaw only the amount of cells on an as-needed basis, saving the customer time and money while minimizing needless waste.

14. Another advantage of using the LiverPool™ products is that the variability observed from study-to-study is less than that of a method of thawing individual vials and pooling them after the first thaw. The LiverPool™ products reduce the variability from study-to-study, day-to-day, and from lab-to-lab. The reduced variability also saves time and money for our customers.

15. The LiverPool™ products also provide several advantages over the pooled cryopreserved hepatocyte products sold by CellzDirect. I am aware of at least four examples from customer feedback, as well as from our own understanding of CellzDirect's products and the LiverPool™ products. First, the LiverPool™ products exhibit consistent activity. In contrast, some customers have found that the activity data associated with CellzDirect's 3A4 products was unreliable. Second, the LiverPool™ products exhibit consistent cell yield from vial-to-vial. In contrast, some customers have found that the number of cells recovered from the CellzDirect vials were not as high as

the cell count listed in the CellzDirect product literature. Third, the LiverPool™ products exhibit high viability. In contrast, customers have found that the percentage viability of thawed vials of CellzDirect's products was lower then what is promoted in the CellzDirect product literature. Lastly, the LiverPool™ products may be customized according to the customer's research needs or specifications to meet specific characteristics (*e.g.*, create a new lot of LiverPool™ to match existing individual donors or an existing pooled product). In contrast, we are unaware that the CellzDirect products are customizable to customer's needs and specifications.

Executed on this 22nd day of June 2010 in Baltimore, Maryland.



Daniel Dryden